

MAY - 8 1997

K970469

## II. SUMMARY AND CERTIFICATION

### Summary of Safety and Effectiveness

#### Manufacturer:

EndoVascular Technologies, Inc.  
1460 O'Brien Drive  
Menlo Park, CA 94025-1436  
Contact: Luanne Termeer

#### Device Name:

The EVT® AngioScale™ angiographic catheter is a diagnostic intravascular catheter, 21 CFR 870.1200, Class II.

#### Substantial Equivalence:

The EVT® AngioScale™ angiographic catheter is substantially equivalent to the Cordis Standard and High Flow Femoral-Ventricular Pigtail Catheters (K862006, Class II), the Cordis 5.2 French Super Torque Plus Cardiology Catheter (K914007, Class II), the Cordis Quanticor Marker Catheter (Class II), and the Cordis Ducor Angiographic Catheter (Class II).

#### Device Description:

The EVT AngioScale angiography catheter is a PEBAX pigtail catheter with 11 to 20 radiopaque platinum marker bands on the catheter tubing. This 6 - 7 French catheter rides over a .038" guide wire. A standard polycarbonate luer adapter at the proximal end allows for injection of contrast media. Distal ports disperse the contrast media for angiographic visualization.

The EVT AngioScale angiography catheter has multiple radiopaque platinum marker bands so that the entire length of the marked catheter image can be used as a scaled ruler.

The EVT AngioScale angiography catheter is provided sterile to the end user. It is disposable, with a useable life of one procedure.

#### Intended Use:

The EVT AngioScale angiography catheters provides angiographic visualization and linear measurement of the vasculature when combined with the delivery of radiopaque contrast media to selected sites in the vascular system.